

In the claims:

Please cancel claims 1-25 without prejudice and add new claims 26-72 as follows:

26. (New) A sustained release formulation comprising one or more biologically active molecules prepared by exposure of the biologically active molecules to an organic solvent under conditions wherein a precipitate, lyophilate or crystal is formed.
27. (New) The formulation of claim 26, wherein the biologically active molecules are released from the formulation for a period of at least 24 hours.
28. (New) The formulation of claim 27, wherein the period is at least 48 hours.
29. (New) The formulation of claim 27, wherein the period is at least 7 days.
30. (New) A sustained release formulation comprising precipitate, lyophilate or crystals of a polypeptide prepared by exposure of the polypeptide to an organic solvent, which polypeptide is released from the formulation in aqueous solution over a period of at least 24 hours.
31. (New) The formulation of claim 30, wherein the period is at least 48 hours.
32. (New) The formulation of claim 30, wherein the period is at least 7 days.
33. (New) A sustained release formulation comprising precipitate, lyophilate or crystals of a biologically active polypeptide prepared by exposure of the polypeptide to a polar protic organic solvent, which formulation, when administered to a patient, releases said polypeptide at a rate which provides an average steady state concentration of at least the ED₅₀ for the polypeptide for a period of at least 2 days.
34. (New) The formulation of claim 33, wherein the period is at least 7 days.
35. (New) The formulation of claim 33, wherein the period is at least 14 days.
36. (New) The formulation of claim 33, wherein the period is at least 21 days.
37. (New) The formulation of claim 33, wherein the period is at least 50 days.
38. (New) The formulation of claim 33, wherein the period is at least 100 days.
39. (New) The formulation of any of claims 26, 30 and 33, wherein the organic solvent is an alcohol, an aldehyde, a ketone, a hydrocarbon, an aromatic hydrocarbon, or a mixture thereof.
40. (New) The formulation of any of claims 26, 30 and 33, wherein the organic solvent is an alcohol or mix of alcohols.

41. (New) The formulation of claim 39, wherein the alcohol is a lower alcohol, or mixture thereof.
42. (New) The formulation of claim 39, wherein the alcohol is selected from the group consisting of methanol, ethanol, isopropanol, n-propanol, n-butanol, isobutanol, and t-butanol, or a mixture thereof.
43. (New) The formulation of claim 26 or 30, wherein the organic solvent is a polar protic solvent.
44. (New) The formulation of claim 26 or 30, wherein the organic solvent is a water-miscible polar protic solvent.
45. (New) The formulation of claim 33, wherein the organic polar protic solvent is water-miscible.
46. (New) The formulation of any of claims 26, 30 and 33, wherein the biologically active molecules or polypeptides are released from the formulation in vivo at a rate which provides an average steady state concentration of at least the ED₅₀ for the biologically active molecules or polypeptides for a period of at least 2 days.
47. (New) The formulation of claim 46, wherein the period is at least 7 days.
48. (New) The formulation of claim 46, wherein the period is at least 14 days.
49. (New) The formulation of claim 46, wherein the period is at least 21 days.
50. (New) The formulation of claim 46, wherein the period is at least 50 days.
51. (New) The formulation of claim 46, wherein the period is at least 100 days.
52. (New) The formulation of any of claims 26, 30 and 33, wherein the organic solvent(s) are chosen such that, when administered to a patient, the solvent is released from the formulation at a rate which provides an average steady state concentration which remains at least one order of magnitude below the IC₅₀ for deleterious side effects, if any, of the solvent.
53. (New) The formulation of claim 26, wherein biologically active molecule is a polymer selected from the group consisting of a peptide, a nucleic acid, an oligonucleotide, a carbohydrate, a ganglioside, or a glycan.
54. (New) The formulation of claim 26, wherein the biologically active molecule is a polypeptide.
55. (New) The formulation of claim 30, 33 or 54, wherein the polypeptide is selected from the group consisting of cytokines, growth factors, somatotropin, growth hormones,

colony stimulating factors, erythropoietin, plasminogen activators, enzymes, T-cell receptors, surface membrane proteins, lipoproteins, clotting factors, anticlotting factors, tumor necrosis factors, transport proteins, homing receptors, and addressins.

56. (New) The formulation of claim 30, 33 or 54, wherein the polypeptide is selected from the group consisting of rennin; human growth hormone; bovine growth hormone; growth hormone releasing factor; parathyroid hormone; thyroid stimulating hormone; lipoproteins; α -1-antitrypsin; insulin; proinsulin; follicle stimulating hormone; calcitonin; luteinizing hormone; glucagon; a clotting factor such as factor VIIIc, factor IX, tissue factor, and von Willebrands factor; anti-clotting factors; atrial natriuretic factor; lung surfactant; a plasminogen activator; bombesin; thrombin; hemopoietic growth factor; tumor necrosis factor- α ; tumor necrosis factor- β ; enkephalinase; RANTES (regulated on activation normally T-cell expressed and secreted); human macrophage inflammatory protein (MIP-1- α); a serum albumin; mullerian-inhibiting substance; relaxin A-chain; relaxin B-chain; prorelaxin; gonadotropin-associated peptide; a microbial protein; DNase; inhibin; activin; vascular endothelial growth factor (VEGF); receptors for hormones or growth factors; integrin; protein A; protein D; rheumatoid factors; a neurotrophic factor; platelet-derived growth factor (PDGF); a fibroblast growth factor; epidermal growth factor (EGF); transforming growth factors (TGF); insulin-like growth factor-I; insulin-like growth factor-II; des(1-3)-IGF-I (brain IGF-I); insulin-like growth factor binding proteins; CD proteins; erythropoietin; osteoinductive factors; immunotoxins; an interferon; colony stimulating factors (CSFs); interleukins (ILs); superoxide dismutase; T-cell receptors; surface membrane proteins; decay accelerating factor; antigens; transport proteins; homing receptors; addressins; regulatory proteins; immunoglobulin-like proteins; antibodies; and nucleases, or fragments thereof.
57. (New) The formulation of claim 26, wherein biologically active molecule is selected from the group consisting of a lipid and a sterol.
58. (New) The formulation of claim 26, wherein the biologically active molecule is a small organic compound.
59. (New) The formulation of any of claims 26, 30 and 33, which is a precipitate.
60. (New) The formulation of any of claims 26, 30 and 33, which is a lyophilate.
61. (New) A formulation comprising a lyophilate of a polypeptide, which lyophilate is formed from a solution including a polar protic organic solvent, and has a solubility rate in a bodily fluid over a period of at least 24 hours that is at least 2 fold less than a lyophilate of the polypeptide from aqueous solution.

62. (New) The formulation of claim 61, wherein the period is at least 48 hours.
63. (New) The formulation of claim 61, wherein the period is at least 168 hours.
64. (New) The formulation of claim 61, wherein the solubility rate is at least 10 fold less than a lyophilate of the polypeptide formed from aqueous solutions.
65. (New) The formulation of claim 61, wherein the solubility rate is at least 25 fold less than a lyophilate of the polypeptide formed from aqueous solutions.
66. (New) The formulation of claim 61, wherein the bodily fluid is serum.
67. (New) A medicament for administration to an animal, comprising the formulation of any of claims 26, 30 and 33.
68. (New) The medicament of claim 67, for administration to a mammal.
69. (New) The medicament of claim 67, for administration to a human.
70. (New) A method for manufacturing a medicament comprising formulating the formulation of any of claims 26, 30 and 33 with a pharmaceutically acceptable excipient.
71. (New) A method for manufacturing a slow release formulation of a biologically active molecule, comprising (a) exposing said biologically active molecules to an organic solvent, and (b) forming a precipitate, lyophilate or crystal.
72. (New) Use of a sustained release formulation of any of claims 26, 30 and 33, in the manufacture of a pharmaceutical preparation in single dosage form.